United States Court of Appeals

for the Second Circuit

BRIEF FOR APPELLANT

76-1353

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United States Court of Appeals

For the Second Circuit

UNITED STATES OF AMERICA,
Appellee,

against

MARCEN LABORATORIES, INC., a corporation, and
RAPHAEL A. MAROTTA, an individual,
Defendants-Appellants.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK.

BRIEF FOR DEFENDANTS-APPELLANTS.

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DEFENDANTS-APPELLANTS' BRIEF.

ISSUES.

Whether section 321(p) of the Federal Food, Drug & Cosmetic Act is unconstitutionally vague on its face and as applied in this case?

Whether the statutory sections upon which the information is based are unconstitutional in that they contain a test of criminality based upon subjective reputation hearsay, precluding appellants from confronting their accusers?

STATEMENT OF THE CASE.

The United States proceeding by information before the U. S. District Court (Judge MacMahon presiding) charged Marcen Laboratories, Inc. and Raphael A. Marotta,

individually, with misdemeanor violations of the Federal Food, Drug & Cosmetic Act. Appellants were charged with violating 21 USC §331 (d) by unlawfully introducing and delivering into interstate commerce certain drugs alleged to be new drugs within the meaning of 21 USC §321 (p). These drugs did not have an effective approval of application required of new drugs by 21 USC §355 (a).

Appellants maintain that 21 USC §321 (p) is unconstitutionally vague and cannot support a criminal prosecution. That section provides in relevant part that a drug is a new drug if its composition

> "is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof * * *"

The parties stipulated that appellants would plead guilty on condition that the question of the statute's constitutionality would be passed upon by the District Court and, in the event the statute was held to be constitutional, the question would be preserved for appeal.

The parties further agreed that appellants would be permitted to withdraw their guilty pleas if the court found the statute unconstitutional.

On January 20, 1976, Marcen Laboratories pled guilty to counts 21, 22, 24 and 30; Mr. Marotta pled guilty to count 31 of the information. On June 11, 1976, the District Court denied appellants' motion to dismiss the information on the ground of unconstitutional vagueness.

Appellants were sentenced on July 27, 1976. Marcen Laboratories, Inc. was fined $4,000. Mr. Marotta was sentenced to 10 days in prison and fined $1,000. This case comes before the Court of Appeals directly on appeal from that decision.

Appellants concede certain facts in the case. They admit that Marcen Laboratories actually caused the pharmaceutical items in question to be transported, that there were no new drug applications for these drugs, and that the Food & Drug Administration notified them on numerous occasions that the drugs in question were considered by the Food & Drug Administration to be new drugs within the meaning of the Food, Drug & Cosmetic Act.

The government concedes that each time the Food & Drug Administration advised appellants the items were considered new drugs, appellants responded that the drugs were *not* new drugs (Appendix, pp. 71a, 72a). Appellants introduced as Exhibit A in the court below (Appendix, p. 78a)

a 1969 stipulation and order withdrawing the Marcen Laboratories, Inc. claim and answer in a seizure case. Appellants made their withdrawal without prejudice to any other litigation and without admitting the allegations in the complaint. Marcen Laboratories, Inc. agreed to discontinue marketing nine of the 16 items involved in that proceeding. With respect to the seven remaining drugs, Marcen Laboratories agreed to revise its promotional materials and submit them to the Food & Drug Administration. The seven drugs included those named in the counts to which appellants pled guilty.

STATUTES INVOLVED.

"Title 21, Sec. 331. The following acts and the causing thereof are prohibited:

"(d) The introduction or delivery for introduction into interstate commerce of any article in violation of Sec. 344 or 355 of this title."

"Sec. 344. Emergency permit control - conditions of manufacturing, processing, etc., as health measures.

"(a) Whenever the secretary finds after investigation that the distribution in interstate commerce of any class of food may, by

reason of contamination with micro-organisms during the manufacture, processing, or packing thereof in any locality, be injurious to health, and that such injurious nature cannot be adequately determined after such articles have entered interstate commerce, he then, and in such case only, shall promulgate regulations providing for the issuance to manufacturers, processors, or packagers of such class of food in such locality, of permits to which shall be attached such conditions governing the manufacture, processing, or packaging of such class of food for such temporary period of time, as may be necessary to protect the public health; and after the effective date of such regulation, and during such temporary period, no person shall introduce or deliver for introduction into interstate commerce any such food manufactured, processed, or packed by any such manufacturer, processor, or packer unless such manufacturer, processor, or packer holds a permit issued by the secretary as provided by such regulations.

"Violations of permit: suspension and reinstatement

"(b) The secretary is authorized to suspend immediately upon notice any permit issued under authority of this section if it is found that any of the conditions of the permit have been violated. The holder of a permit so suspended shall be privileged at any time to apply for reinstatement of such permit, and the secretary shall, immediately after prompt hearing and an inspection of the establishment, reinstate such permit if it is found that adequate measures have been taken to comply with and maintain the conditions of the permit, as originally issued or as amended.

"Inspection of permit-holding establishments

"(c) Any officer or employee duly designated by the secretary shall have access to any factory or establishment, the operator of which holds a permit from the secretary, for the purpose of ascertaining whether or not the conditions of the permit are being complied with, and the denial of access for such inspection shall be ground for suspension of the permit until such access is freely given by the operator."

"Sec. 355. New drugs - Necessity of effective approval of application

"(a) No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) of this section is effective with respect to such drug.

"Filing application; contents

"(b) Any person may file with the Secretary an application with respect to any drug subject to the provisions of subsection (a) of this section. Such person shall submit to the Secretary as a part of the application (1) full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use; (2) a full list of the articles used as components of such drug; (3) a full statement of the composition of such drug; (4) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug; (5) such samples of such drug and of the articles used as components thereof as the Secretary may require; and (6) specimens of the labeling proposed to be used for such drug."

"Sec. 321.

"(p) The term "new drug" means -

"(1) Any drug (except a new animal drug or an animal bearing or containing a new animal drug) the composition of which is such that such drug is not generally recognized, and experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof, except that such a drug not so recognized shall not be deemed to be a "new drug" if at any time prior to the enactment of this chapter it was subject to the Food and Drug Act of June 30, 1906, as amended, and if at such time its label contained the same representations concerning the conditions for its use; or

"(2) Any drug (except a new animal drug or an animal bearing or containing a new animal drug) the composition of which is such that such drug, as a result of investigations to determine its safety and effectiveness for use under such conditions has become so recognized,

but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions."

"Sec. 333. Penalties - Violation of section 331 of this title.

"(a) Any person who violates a provision of section 331 of this title shall be imprisoned for not more than one year or fined not more than $1,000 or both."

POINT I.

THE STATUTE UPON WHICH THE INFORMATION IS BASED IS UNCONSTITUTIONALLY VAGUE ON ITS FACE AND AS APPLIED IN THE INSTANT CASE.

The law is well established that, to be constitutional, a criminal statute "must be informative on its face *** and so explicit that 'all men subject to its penalties may know what acts it is their duty to avoid.'" *U. S. v. Brewer*, 139 U. S. 278, 288 (1891). Courts hearing vagueness issues not involving the First Amendment must consider the vagueness challenge "not only in terms of the statute on its face, but also in light of the conduct to which it is applied." *U. S. v. National Dairy Corp.*, 372 U. S. 29, 36 (1963). Appellants submit that the statute in question suffers from both weaknesses.

The "new drug" definition of the Federal Food, Drug & Cosmetic Act has been challenged once before in a criminal case. *U. S. v. The Dow Corning Corporation*, Cr. No. 5381 (E. D. Mich., June 14, 1968), was an unreported case in which the defendant contended the statutory definitions of "drug," "device," "cosmetic" and "new drug" were so vague that no one could reasonably distinguish between them. The court held, contrary to later U. S. Supreme Court rulings,[1] that the statute did not require clarification. Thus, the Michigan case neither served to warn Mr. Marotta or Marcen Laboratories, Inc., nor did it aid them in construing the statute. Therefore, appellants' case will be the first major criminal case on this issue and should be reviewed as such.

The statute is vague insofar as the sections cumulatively attempt to create a criminal offense. The government has conceded that the statute is vague on its face (Appendix, pp. 60a, 61a). In order for an individual to determine what is proscribed, she or he must begin with Section 331 which makes introducing certain articles into interstate commerce a crime. Those articles are described in Sections 344 and 345, whose complications and vaguenesses created the necessity for Section 321, the definition section of the Federal Food, Drug & Cosmetic Act.

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1. To be discussed, *infra*, at 12.

Appellants submit that in its attempt to clarify the statute's language, Congress totally obfuscated the statute's meaning for purposes of criminal prosecution.

As previously noted, Section 321 (p)(1) provides that a "new drug" is "any drug *** the composition of which is such that such drug is not *generally recognized, among experts****" (Emphasis added.) "Generally recognized" and "among experts" are not terms which an individual in the drug industry can readily define from his or her trade experience, as appellants' encounters with the Food & Drug Administration indicate. The statutory test is general and subjective. It is to be carried out by the collective opinion of an undefined group.

The government maintains that, although the statute is vague, the language should be interpreted in light of the facts of this specific case and in light of civil cases which define the sections in question.

Appellants clearly had notice that the Food & Drug Administration considered appellants' drugs to be new drugs within the meaning of the statute. However, appellants constantly disputed with the Food & Drug Administration's declarations, arguing that their drugs had been on the market since before 1935. These continuing arguments between appellants and the government certainly did not clarify anything.

The prosecution points to *Weinberger v. Hynson, Westcott & Dunning, Inc.*, 412 U. S. 609 (1973), which upheld the definition of "new drug" for the purposes of civil enforcement. Such a case cannot serve to clarify a vague criminal statute. Civil interpretation should not create criminal responsibility. That is the work of the legislature. The Supreme Court further construed the statute in *Weinberger v. Bentex Pharmaceuticals, Inc.*, 412 U. S. 645 (1973), when it held that a Food & Drug Administration declaration that any given drug is a new drug is an authoritative determination of that drug's status.[2]

Both *Weinberger* cases were civil cases. Upon possible later presentation of general recognition evidence, the Food & Drug Administration would revoke its order refusing approval of the new drug application as provided by Section 355 (f). The company could then resume its activities. The situation is not so simple for criminal cases.

As a result of the 1973 Supreme Court decisions, any Food & Drug Administration's declaration that a drug is new stands as proof that it is a new drug. The government need only prove beyond a reasonable doubt that the defendant introduced the drug into interstate commerce and the defendant is proven guilty. There is no requirement that the administrative ruling be questioned. In

2. *Id.* at 653.

fact, in light of the *Weinberger v. Bentex* case, it would seem the Food & Drug Administration's ruling would be unassailable in criminal trials.

The government maintained in its brief that it would prove its case against appellants, had the matter gone to trial, by introducing experts to testify as to the drugs' lack of general recognition. There is no statutory requirement to that effect. The government hoped by its courtroom conduct to gloss over the fact that it otherwise would have had to rely on an unquestionable administrative decision.

Should a defendant be fined or imprisoned, a Section 355 (f) proceeding could not restore the defendant. To expect this vague statute coupled with administrative fiat to pass as a valid criminal law is outrageously unjust.

POINT II.

THE STATUTORY SECTIONS UPON WHICH THE INFORMATION IS BASED ARE UNCONSTITUTIONAL IN THAT THE TEST OF CRIMINALITY IS BASED UPON SUBJECTIVE REPUTATION HEARSAY WHICH PRECLUDES APPELLANTS FROM CONFRONTING THIER ACCUSERS.

Even if it were established that the government must introduce proof of general recognition to win its case, imagine the burden that would fall to the defendant. An expert would testify as to the subjective reputation of

the pharmaceutical items in issue (Appendix, p. 68a). For example, the witness might say, "I understand that the drug is not generally recognized by my colleagues." Thus the issue as framed by the statute is not what the testifying expert's opinion is concerning the drug itself, but what the witness knows of the drug's reputation. The true accuser here is not the testifying expert. Rather, it is that general class of experts who have come to a negative opinion concerning the drugs' reputations.

A statute which precludes criminality upon overheard subjective opinion cannot be constitutional. Cross-examination of the individual experts, those who *in toto* establish the pharmaceutical reputation which renders introduction of the drug item criminal or non-criminal, can not be had. This mass of people can not be examined as to their sources of information or the tests which they made upon the drugs in question - the controls of the experiments, the statistics, etc.

The Sixth Amendment states that "in a criminal prosecution the accused shall enjoy the right *** to be confronted with the witness against him." The statute here predicates criminality upon the absence of a drug's positive reputation among a body of experts the defendant can not question. Appellants submit that the statute violates the Sixth Amendment.

POINT III.

THE PRISON SENTENCE OF THE INDIVIDUAL APPELLANT WAS EXCESSIVE.

Appellant, Raphael A. Marotta, has been sentenced to ten days in prison and fined $1,000, the maximum fine. It is submitted that the jail sentence was excessive.

Mr. Marotta, at age 69, faced his first involvement with the law in this case. He pled guilty to one count of a misdemeanor information. As a result of the involvement in this case Mr. Marotta lost his business, suffering substantial economic loss. There was nothing in Mr. Marotta's background or the nature of the violation to justify a jail sentence. Due to the poor wording of the statute Mr. Marotta believed he was violating no law and persisted in refusing to go out of business. He fought the Government seizures and refused to capitulate. His one-man business continued in the face of frequent Government seizures. This tenacity does not warrant a jail sentence. This is particularly so in view of his wife's ill health and his excellent record to age 69. The economic loss concomitant with his fine and loss of business actually exceeded the maximum statutory fine and clearly satisfied the punitive provision of the misdemeanor statute.

The jail sentence ought be set aside as excessive.

CONCLUSION.

For the foregoing reasons, the judgment of the District Court should be reversed or the prison sentence should be set aside.

Respectfully submitted,

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Attorney for